

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Dr. Keith Reding  
Monsanto Company  
700 Chesterfield Parkway North  
St. Louis, MO 63198

JAN - 8 1998

Dear Dr. Reding,

This is in regard to your genetically modified NewLeaf Y potato lines about which you initiated consultations with the Agency on July 31, 1997. According to Monsanto, the NewLeaf Y potato lines have been modified to be Colorado Potato Beetle and Potato Virus Y resistant through the expression of the CryIIIa protein from *Bacillus thuringiensis* subsp. *tenebrionis* and the PVY coat protein from Potato Virus Y.

As part of bringing your consultation with FDA regard this product to closure, you submitted a summary of your safety and nutritional assessment of the NewLeaf Y potato lines on July 31, 1997. These communications informed FDA of the steps taken by Monsanto to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that the NewLeaf Y potato lines are not materially different in composition, safety, or other relevant parameters from potatoes currently on the market, and that they do not raise issues that would require premarket review or approval of FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 000049 and will be maintained by the Office of Premarket Approval.

Based on the information Monsanto has presented to FDA, we have no further questions concerning the NewLeaf Y potato lines ( NewLeaf Y cv. Russet Burbank (RBMT15-101), NewLeaf Y cv. Shepody (SEMT15-02, SEMT15-07, and SEMT 15-15) and NewLeaf Y cv. Hi-Lite (HLMT15-3, HLMT15-15, HLMT15-46)) at this time. However, as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph. D.  
Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition